

REGULATORY AFFAIRS  
DEPT. 956

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ					

L May-09-84	MEETING REQUEST MTC 5/22: POSSIBILITY OF MULTIPLE-DOSE CLASSIFICAT'n	GRP	831426	
L May-18-84	INITIAL SUBMISSION 166 VOLUMES. BREAST INDICATION	DRS	831482	
	(a) TABLE OF CONTENTS vols 1.1 - 1.26; OPTIONAL EXPANDED SUMMARY			
	(b) LABEL # /PT 4 vol 1.26			
	(c) COMPONENTS & COMPOSITION # /PT 6,7 vol 1.26			
	(d) MANUF & CONTROLS vol 1.27-8			
	(e) PRECLINICAL # /PT 10 vols 1.29 - 1.39; RPT Nos. 1-159			
	(f) BIOPHARMACEUTIC PKG vols 1.40-44			
	(g) BIBLIOGRAPHY vols 1.45-48			
	(h) DRUG EXPER RPT vols 1.49-50			
	(i) CLINICAL STUDIES vols 1.51-2; PHARMACOKINETIC STUDIES			
	(j) CLINICAL STUDIES vols 1.53-77; DOSE TOLERANCE STUDIES			
	(k) CLINICAL STUDIES vol 1.78 - 1.150; CONTROLLED STUDIES			
	(l) CLINICAL STUDIES vols 1.151-155; OTHER CLINICAL STUDIES			
	(m) CLINICAL STUDIES vol 1.156; CLINICAL LAB STUDIES RELATED TO SAFETY			
	(n) CLINICAL STUDIES vols 1.157 - 1.166; SPECIAL PATIENTS			
L Oct-24-84	CORRESPONDENCE PATENT & EXCLUSIVITY INFO PER McGINNIS' REQUEST, 10/23/84	ECM	831985	
L Nov-12-84	L Oct-24-84	CORRESPONDENCE PATENT & EXCLUSIVITY INFO (CORRECTS 10/24/84 COMMUNICATION)	GWM	832039

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19-297	NDA	NOVANTRONE *MITOXANTRONE INJ			
L Nov-28-84		CORRESPONDENCE	84-66	DJF	832068
		(a) SUMMARY, CLINICAL PROPOSED DRAFT SUMMARY BASIS OF APPROVAL			
L Jan-23-85		CORRESPONDENCE AS REQUESTED BY CSO ALETA SINDELAR		DJF	850044
		(a) PUBLISHED RPTS METASTATIC BREAST CANCER (CANCER CLIN TRIALS 4:355-362, '81)			
L Apr-17-85		MEETING AGENDA FOR 5/2/85 MTG re RESUBMN OF CLIN DATA FOR META BR CA		DJF	850327
L May-28-85	M May-02-85	CORRESPONDENCE REVIEW OF LED's UNDERSTANDING OF THE 3/28 & 5/2/85 MEETINGS		DJF	850508
L Jul-12-85	L May-18-84	NOT APPROVABLE LED MUST SUBMIT AMENDMENT CORRECTING DEFICIENCIES		DJF	850714
L Oct-21-85	F Jul-12-85	AMENDMENT RESUBMISSION FOR BREAST INDICATION (INIT'L SUBM 5/18/84)		DJF	851114
F Nov-20-85	L Oct-21-85	CORRESPONDENCE 10/21/85 SUBM CONSIDERED MAJOR AMNDMT - NEW 180 DAY REVIEW PD		DJF	851157
L Nov-20-85	F Jul-12-85	AMENDMENT RESPONSE TO 7/12 DEFIC LTR re MANUF/CTRLS NOT ADDRESSED 10/18		DJF	860081
		(a) LABEL-REVISED DRAFT, CONTAINER # 17312 TEXT CODE: PRD2 10ml VIAL			
		(b) LABEL-REVISED DRAFT, BOX # 17311 TEXT CODE: PRD2 10ml VIAL			

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- (c) LABEL-REVISED DRAFT, CONTAINER # 17313  
TEXT CODE: PRD2  
15ml VIAL
- (d) LABEL-REVISED DRAFT, BOX # 17314  
TEXT CODE: PRD2  
15ml VIAL
- (e) LABEL-REVISED DRAFT, BOX # 17310  
TEXT CODE: PRD2  
12.5ml VIAL
- (f) LABEL-REVISED DRAFT, BOX # 17309  
TEXT CODE: PRD2  
12.5ml VIAL
- (g) LABEL-REVISED DRAFT, PKG INSERT # 17303  
TEXT CODE: PRD4
- (h) FORMULATION # /PT 7  
COMPOSITION OF BOTH CLIN FORM'Ns I & II (PROPOSED  
COMM'1 FORM)
- (i) CONTROLS # /PT 8(c)  
IN-PROCESS CTRLS--GOSPORT PRODUCTION (PER ITEM#2,  
7/12 LTR)
- (j) MONOGRAPH # /PT 8(d)  
SPECS FOR RAW MATERIAL & COMPONENTS
- (k) AUTHORIZATION # /PT 8(n)  
HALDANE & WICKHAM LABS LTRS AUTH'g FDA TO X-REF  
THEIR DMFS
- (l) STABILITY # /PT 8(p)  
SUMMARY & REPORTS
- (m) ANALYSES  
REPORT OF ANALYTICAL FINDINGS FOR CL 232,315

L Dec-06-85 L Oct-21-85 CORRESPONDENCE DJF 851175  
REPL PAGES (REPRESENTING CORRECTIONS) v2.41 pp  
75-77, 87, 89

L Jan-10-86 AMENDMENT GRP 860021

- (a) MANUF & CONTROLS  
HEINRICH MACK NACHF. AMNDMT TO DMF#5203 FOR MANUF  
MITO BULK

L Jan-20-86 L Oct-21-85 CORRESPONDENCE DJF 860032

- (a) CLINICAL STUDIES  
REANALYSIS OF DURATION OF RESPONSE DATA (NO  
SIGNIFICNT DIFF)

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L Jan-23-86		CORRESPONDENCE LIST OF INDIVIDUALS PARTICIPATING IN 3/6/86 ONCUL ADVIS MTNG		DJF		860066	
L Jan-23-86		CORRESPONDENCE		DJF		860068	
	(a)	SUMMARY, CLINICAL 20 COPIES FOR ADVISORY COMM REVIEW/MTG 3/6; NOT FILED IN NDA					
F Jan-27-86	L Nov-20-85	CORRESPONDENCE 11/20/85 AMNDMT DEEMED "MAJOR" --ADDL 2mo ADDED TO REVIEW PD		DJF		860074	
L Jan-28-86		CORRESPONDENCE		DJF		860067	
	(a)	CASE REPORT FORM LISTING OF CRF's (AS REQ'd BY TURNER) FROM 10/18/85 SUBM					
L Feb-05-86		TELEPHONE CALL MR. MEYER re FEASABILITY OF CYAN SPONSRSHP OF ADVIS COMM MTG		ECM		870059	
F Feb-18-86	L Jan-10-86	CORRESPONDENCE 1/10/86 AMNDMT DEEMED "MAJOR" --REVIEW PD EXT 1 Mo.--7/23/86		GRP		860127	
L Feb-25-86	L Oct-21-85	CORRESPONDENCE		DJF		860146	
	(a)	SAFETY UPDATE - CLINICAL SAFETY UPDATE OF 10/21/85 RESUBMISSION					
L Feb-26-86	T Feb-13-86	CORRESPONDENCE RESPONSE TO BURKE'S ?? re CARDIOTOX RPT - v2.40, 10/21 RESUB		DJF		860152	
B Mar-14-86		MEETING ADV COMM MTG (9-2 FAVOR NOVANT "ALTERNATIVE" TO ADRIA IN MBC		ECM		870060	

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L Mar-19-86	M Mar-14-86	CORRESPONDENCE GLOSSIES OF SLIDES USED IN LED PRES'n AT ADVIS COMMITTEE MTG	DJF	860226
L Mar-24-86	M Mar-14-86	CORRESPONDENCE MEMO TO SUTHERLAND: FOLLOW-UP REMARKS OF MTG(APPRVL TIMETBL)	ECM	870061
F May-30-86	L May-18-84	NOT APPROVABLE MANUFg, STABILITY, LABELING, CLINICAL PHARM, PK DEFICIENCIES	DJF	860528
L Jun-09-86	F May-30-86	AMENDMENT RESPONSE TO MANUF'g & CONTROL DEFICIENCIES NOTED IN 5/30 LTR  (a) MANUF & CONTROLS # 15201f(g) /PT 8h (b) FORMULA & SOI # /PT 8b (c) STABILITY REPORT # 86-494 /PT 8n 2mg/ml, UPDATE RPT	GRP F	860538
L Jun-10-86	F May-30-86	CORRESPONDENCE AS REQ'd, 4 COPIES OF METHODS VALIDATION PACKAGE	GRP	860537
L Jul-16-86	F May-30-86	CORRESPONDENCE  (a) LABEL # 14545 TEXT CODE: PRD5 INSERT PROPOSED BY FDA w/ LEDERLE ALTERNATIVE WORDg/DELET'Ns	DJF	860669
L Aug-04-86		VALIDATION AS PER FDA CHEMIST (DR TOLGYESI) INSTRUCTIONS	GRP	860719

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		(a) SAMPLES 1x5gm SAMPLES (CGBL & WG) & REFERENCE STNDS FOR VALIDATIONS					
L Aug-06-86		VALIDATION SAMPLES/REFERENCES STNDS TO BE USED FOR VALIDATION STUDIES		GRP		860756	
F Aug-19-86	L Jul-16-86	CORRESPONDENCE 7/16/86 AMNDMT DEEMED "MAJOR"; ADDL 60 DAYS FOR REVIEW PD		GRP		860704	
F Sep-08-86	L Jun-10-86	CORRESPONDENCE JUNE 9&10 AMDMTS "MAJOR" --2mo ADDED TO REVIEW PD: 8/10/86		DJF		860827	
F Oct-07-86		NOT APPROVABLE		DJF		861059	
L Oct-17-86		MEETING LED REQUESTS MTG re FURTHER REQMRNTS FOR NDA APPROVAL		DJF		861033	
L Nov-24-86	M Dec-18-86	MEETING PROPOSED AGENDA & LIST OF LED ATTENDEES FOR 12/18/86 MEETING		DJF		870718	
L Dec-10-86	M Dec-18-86	MEETING BACKGROUND INFO FOR UPCOMING MTG, 12/18/86	86-40	DJF		870731	
L Mar-12-87	L Jun-23-27	AMENDMENT DATA TAPES W/FULL RPTS OF REFORMATTED SUMMARY TABLES		DJF		870982	
L Mar-12-87	L Dec-18-86	MEETING INTENT TO SUBMIT FULL RE-EVAL. & CLIN.SUMMARY OF 4-52		DJF		870981	
		(a) CORRESPONDENCE INTENT TO SUBMT RE-EVAL. & CLIN SUMMARY OF STDY 4-52					

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L Mar-19-87 F May-30-86 AMENDMENT DJF 870977  
21 PRECLINICAL RPTS/9VOL INCLUDING FULL SUMMARIES  
FOR 3 STD'S

(a) PRECLINICAL REPORT(s)  
REQUEST FROM FDA-TEL 6/23 & 8/27

F Apr-23-87 Y Mar-12-87 \* TELEPHONE CALL DJF L 870291  
DR G BURKE, MRO

RE OUR 3/12/87 PROPOSAL FOR UPDATING 4-52, HE  
REQUESTED UPDATED SURVIVAL & CARDIOTOX DATA ALSO  
BE SUBMITTED FOR 3-48. THEY MIGHT ALSO BE  
INTERESTED IN SAME FOR 3-40. WILL CONFIRM IN  
OFFICIAL LETTER.

F Apr-27-87 L Mar-19-87 ACKNOWLEDGEMENT DJF 870976  
SUBM NOT SUFFICIENT-NOT BEING PROCESSED AS  
AMENDMENT

L May-05-87 # TELEPHONE CALL DJF 871452  
DR G BURKE, MRO

DR POSNER CALLED DR BURKE RE BREAST CANCER  
AMENDMENT AND PRE-NDA MTG ON LEUKEMIA. ALSO  
DISCUSSED THE POSSIBILITY OF A TREATMENT IND.

F May-08-87 Y Mar-12-87 # TELEPHONE CALL DJF 870491  
DR KARL LINN, BIOMETRICS

HE INDICATED HE WAS HAVING A PROBLEM READING THE  
CARCINOGENECITY TAPES(SUBMITTED ON 3/12/87) INTO  
HIS COMPUTER. DR GOLDBERG TO CALL HIM BACK ON THE  
MATTER.

F May-14-87 \* TELEPHONE CALL DJF 870502  
DR. CARL LINN, BIOSTAT 5/8/87-TAPES SUBM. 3/12/87

REQUESTED INFO RE CARCINOGENECITY TAPES PROVIDED  
TO FDA ON 3/12/87. DR GOLDBERG PROVIDED  
CLARIFICATION INCLUDING ADDITIONAL TAPE SPECS.

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L May-15-87		CORRESPONDENCE INFO ON EFFECT OF NOV. IN LEUKEMIA IN PREP FOR PRE-NDA MEET		DJF	870636
L May-21-87		# MEETING DR G BURKE, MRO		DJF	871336
		OBTAINED ADVANCED COPY OF FDA LETTER REQUESTING ADDITIONAL DATA ON 3-40 & 3-48.			
F May-28-87		* TELEPHONE CALL MS A SINDELAR,CSO		DJF	870583
		PRE-NDA MTG TO DISCUSS LEUKEMIA FILING ARRANGED FOR JULY 7 AT 1:30PM IN 14B/45 AT FDA. DRS TEMPLE & BOTSTEIN + ONCOLOGY DIVISION STAFF WILL ATTEND.			
L Jun-29-87		MEETING 87-14 PREP FOR PRE-NDA MTG.7/7/87 - SENT TABLE OF CONTENTS		DJF	870969
		(a) CORRESPONDENCE SENT TABLE OF CONTENTS FOR LEUKEMIA FILING			
L Jul-07-87		# MEETING DR. TEMPLE AND ONCOLOGY DIVISION MEMBERS		DJF	870789
L Jul-21-87		CORRESPONDENCE MINUTES OF PRE-NDA MTG W/FDA 7/7/87		DJF	871322
L Jul-21-87		* TELEPHONE CALL DR R TEMPLE, DIRECTOR		DJF	871002
		DR CARTWRIGHT SPOKE WITH DR TEMPLE FOLLOWING UP OUR MTG OF 7/7/87. TEMPLE POSITIVE ABOUT THE LEUKEMIA CLAIM AND ANXIOUS TO RECEIVE DATA ON BREAST & LEUKEMIA ASAP AS THE NEXT ADVISORY MTG IS SCHEDULED FOR EARLY DECEMBER.			

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L Jul-23-87		MEETING DR D HERSEY, SEC ONCOL ADV COMMITTEE		DJF		870911
		NEXT ADVISORY COMMITTEE TENTATIVELY SCHEDULED FOR DECEMBER 7-8, 1987.				
L Jul-28-87		DRUG EXPERIENCE RPT SAFETY EVENT REPORT- NETHERLANDS #3062	87-17	DJF		870961
	(a)	SAFETY UPDATE DEAF & BLIND AFTER TREAMNT-DIED FEW DAYS LATER PAT. #3062				
L Jul-29-87		CORRESPONDENCE LETTER OF AUTHORIZATION FOR SPEITZER	87-18	DJF		870960
	(a)	AUTHORIZATION STDYING ETOPOSIDE&THIO.W/AUTOLOGOUS MARROW SUPPT/BREST CANCR				
L Aug-17-87	*	AMENDMENT RAW DATA FOR UPDATES ON 4-52, 3-40, & 3-48		DJF		871091
	(a)	CASE REPORT FORM FDA REQUESTS: 5/30/86; 10/6/86; 5/10, 1987: PROT 4-52, 3-40, 3-48				
		RAW DATA SUBMITTED FOR BREAST STUDIES 4-52, 3-40, & 3-48				
L Aug-26-87		TELEPHONE CALL DR D HERSEY, SEC ONCOL DRUGS ADV COMM		DJF		871335
		LATEST LIST OF PANEL MEMBERS FROM ADVISORY PANEL REC'D. MTG TENTATIVELY SCHEDULED FOR 12/7&8.				
L Sep-09-87		CORRESPONDENCE RE-REQUEST FOR GOSPORT INSPECTION AFTER 1ST REQ. CANCELLED		CRP		871391
L Sep-11-87	*	TELEPHONE CALL DR J JOHNSON, GR DIRECTOR ONCOLOGY		DJF		871111

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DR JOHNSON RECEPTIVE TO PIECemeAL SUBMISSION OF LEUKEMIA CLAIM. WOULD DO HIS BEST TO REVIEW BEFORE ADVISORY MTG IN DECEMBER.

F Sep-15-87		* TELEPHONE CALL DR G BURKE, MRO		DJF	871117
		REQUESTED CRFS FOR 4-52 RESPONDERS WHOSE RAW DATA WERE NOT INCLUDED IN 8/87 FILING.			
L Sep-16-87		* TELEPHONE CALL DR J JOHNSON, ONCOLOGY GROUP DIRECTOR		DJF	871128
		DISCUSSED SCHEDULE FOR PIECemeAL FILING OF LEUKEMIA CLAIM & CONTENT OF PACKAGE FOR ADVISORY COMMITTEE IN DECEMBER.			
L Sep-16-87		CORRESPONDENCE LIST OF SUBMISSIONS FOR NEXT MONTH FOR BREAST & LEUKEMIA		DJF	871230
L Sep-16-87		CORRESPONDENCE LIST OF RESPONDERS IN THE 4-52 STUDY OF NOV. IN BREAST CANCER		DJF	871229
	(a)	CORRESPONDENCE LIST OF RESPONDERS IN 4-52 STUDY OF NOV. IN BREAST CANCER.			
L Sep-18-87	L Sep-11-87	TELEPHONE CALL		DJF	871199
		NOTIFIED DR. JOHNSON ABOUT PIECemeAL SUBM. OF COMP FOR LEUKEMIA & BREAST WHICH WILL HOPEFULLY ALLOW INCLUSION OF BOTH CLAIMS ON AGENDA FOR ADV. COMM MTG.			
L Sep-21-87		* AMENDMENT CASE RECORDS FOR 3-74 & 3-603 LEUKEMIA TRIALS		DJF	871228
	(a)	CLINICAL STUDIES TRETMNT OF ADLT ACUTE NON-LYMPH LEUKEMIA/OD GRANTED 7/13/87			

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CRF'S FOR 3-74 AND 3-603 FILED TO FDA AS PART OF  
APRECLINICAL SUBMISSION FOR A CLAIM IN ANLL.  
ADDITIONAL SUBMISSIONS PROJECTED FOR SEPTEMBER 30  
AND OCTOBER 15.

L Sep-22-87 TELEPHONE CALL DJF 871130  
DR D HERSEY, SEC ONCOL DRUGS ADV COM

DR ALBERT BERNARTH ADDED TO ONCOLOGIC DRUGS  
ADVISORY PANEL. NO OFFICIAL AGENDA ITEMS  
IDENTIFIED.

L Sep-30-87 F \* AMENDMENT DJF 871198  
5/30/86, 10/7/86, 5/20/87, MTGS: 12/18/86 & 7/7/87

(a) CORRESPONDENCE  
RESPONSE TO PHARMACOK. QUESTIONS FROM FDA LETTER  
5/30/86  
(b) SUMMARY, CLINICAL  
UPDATED 4-52 SUMM./SURV. CURVES  
3-40 & 3-48/CLIN.PHARM.SUMM.

UPDATE OF 4-52, 3-40 AND 3-48 + RESPONSE TO PK  
QUESTIONS-REPRESENTS A FULL RESPONSE TO FDA  
LETTERS 5/30/86, 10/7/86 AND 5/20/87.

L Oct-01-87 \* CORRESPONDENCE DJF 871161  
DR CARTWRIGHT'S COMMENTS TO DR TEMPLE RE BR & LEUK  
SUBMISS.

DR CARTWRIGHT INFORMS DR TEMPLE VIA LETTER ABOUT  
OUR PLANS FOR PIECEMEAL FILINGS FOR THE BREAST AND  
LEUKEMIA CLAIMS.

L Oct-02-87 \* AMENDMENT DJF 871197  
CLINICAL DATA TO SUPP. ADULT ACUTE NON-LYMPHOCYTIC  
LEUKEMIA

(a) CLINICAL REPORT(s) # /PT b  
MULTI-CTR STUDY 3-74+ARA-CVS.CERUBIDINE+ARA-C/11  
SUPP STUDIES  
(b) BIBLIOGRAPHY  
+REPRINTS ITEM #8 REPRES.COMBINED CLIN & STAT  
PRESENTATION

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NDA AMENDMENT INCLUDING CLINICAL REPORTS OF 3-74 & 11 SUPPORTIVE TRIALS + A CLINICAL BIB SUBMITTED TO FDA.

L Oct-09-87 # TELEPHONE CALL DJF 871196

OCT 8 SPOKE W/DR. HERSEY ABOUT PREP FOR ADVISORY COMM. IN DEC. HE NOTED BOTH LEUK. & BREAST CLAIMS FOR NOV. WERE TENTATIVELY ON AGENDA. LEUK-MORNING OF DEC.7 W/ BREAST IN AFTERNOON. CONTINGENT UPON FDA REVIEWING PKGS. SUBM. & ONES TO BE FILED. HE ADDED THAT CRITERIA FOR APPROV. OF A SOLID TUMOR TYPE (OVARIAN CANCER) MIGHT BE AN AGENDA ITEM. NEED TO C/B IN A COUPLE WEEKS FOR MORE INFO.

F Oct-16-87 VALIDATION GRP 880066  
VALIDATION TESTING COMPLETE & SUITABLE  
W/MODIFICATIONS

F Oct-16-87 # VALIDATION GRP 880036  
METHODS VALIDATION APPROVED WITH SOME  
MODIFICATIONS

F Oct-16-87 # TELEPHONE CALL DJF 871265  
DR G BURKE, MRO

SPOKE WITH DR MARCUS RE CASES OF HYPERBILIRUBINEMIA IN 3-74 LEUKEMIC PATIENTS AND CODING/TRANSCRIPTION ERRORS IN DOCUMENTING ADR'S.

L Oct-19-87 \* CORRESPONDENCE DJF 871321  
PROPOSED LABELNG-REQUESTED BY A. SINDELAR  
10/16/87-BREAST

PROPOSED BREAST LABELING FORWARDED TO FDA.

F Oct-20-87 ACKNOWLEDGEMENT DJF 871418  
BR CA DEFICIENCIES: ITEMS 6 (PHARMACO) & 8 (CLIN & STAT)

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L Oct-21-87	L Mar-12-87	CORRESPONDENCE REPLCMNT TAPE-NB8238 RAT CARCINOGEN. STDY #81152		DJF	871320
L Oct-22-87		* CORRESPONDENCE DOCUMENTATION FOR ADVISORY COMM FOR DECEMBER MTG  (a) LABEL-DRAFT, PACKAGE INSERT COVERNG USE IN BOTH LEUKEMIA & BREAST CANCER (b) CLINICAL REPORT(s) MULTICENTER STUDIES: 3-603, NOV + ARA-C VS CERUBIDINE+ARA-C  FINAL INSTALLMENT OF CLINICAL DATA TO SUPPORT THE LEUKEMIA(ANLL) CLAIM FILED AT FDA. SUBMISSION INCLUDES 3-603 CLINICAL REPORT, INTEGRATED SUMMARIES OF SAFETY & EFFICACY AND PROPOSED LABELING COVERING BOTH THE LEUKEMIA & BREAST CA CLAIMS.		DJF	871319
F Oct-28-87		* TELEPHONE CALL DR G BURKE, MRO  PHONED DR S MARCUS REQUESTING INFORMATION ON LEUKEMIA STUDY 3-603 RELATED TO MISSING BONE MARROW DATA & PROBLEMS IN THE PACIFIC REGION.		DJF	871328
F Oct-29-87		# TELEPHONE CALL DR R STEIN, FDA BIOSTATISTICIAN  PHONED DR J GOLDBERG RE QUESTIONS ON THE 4-52 BREAST CA REPORT RELATED TO 80 CUTOFF VALUE FOR SGOT & ESTIMATION OF TTD.		DJF	871348
F Oct-30-87		* TELEPHONE CALL DR G BURKE, MRO  CALLED DR S MARCUS RE HIS RECENT REQUEST FOR THE MISSING BONE MARROW RATING DATA.		DJF	871337
L Nov-02-87		# RESPONSE TO FDA REPLAC OF APP VI TO 3-603 STUDY REQ BY DR BURKE 10/28/87		DJF	871445

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19-297 NDA NOVANTRONE \*MITOXANTRONE INJ

REPLACEMENT OF APP VI OF THE 3-603 STUDY SUBMITTED  
ON 10/22/87 FILED PER DR BURKE'S REQUEST OF  
10/28/87

L Nov-04-87 CORRESPONDENCE DJF 871413  
HANDOUTS FOR 12/7-8/87 ONCOLOG ADV COMM MTG (20  
CC)

L Nov-06-87 CORRESPONDENCE DJF 871417  
REPLACEMENT COPY:APPEND#6 SUB.11/2/87;APPEND#14  
SUB.10/22/87

F Nov-06-87 # TELEPHONE CALL DJF 871376  
DR D HERSEY, SEC ONCOL DRUGS ADV COMM

QUESTIONS FROM ONCOLOGY DIV TO ADVISORY PANEL  
OBTAINED.

L Nov-12-87 PERIODIC REPORT AH 880091  
10/1/86 - 9/30/87

L Nov-12-87 # RESPONSE TO FDA DJF 871446  
LISTING OF LAB CONVERSION FACTORS FILED

A LISTING OF LAB CONVERSION FACTORS FOR THE 3-603  
STUDY FILED PER DR BURKE'S REQUEST.

F Nov-13-87 \* TELEPHONE CALL DJF 871395  
DR G BURKE, MRO

REQUESTED ADD'L ANALYSES OF SURVIVAL, RR & RESPONSE  
DURATION FOR INTENT-TO-TREAT PTS (EXCEPT THOSE  
WRONGLY DIAGNOSED) IN 3-74 & 3-603. ALSO TO RUN  
SAME DELETING HONG KONG & TAIWAN.

L Nov-19-87 # TELEPHONE CALL DJF 871431  
DR G BURKE, MRO



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L Nov-30-87		RESPONSE TO FDA COPIES OF 3-74 VOLS(LEUK) TO DR G TURNER AS REQUESTED	DJF	871440
		(a) CORRESPONDENCE FDA REQ FOR VOL 1,2,3(14.1,14.2,14.3)LEUKEMIA 3-74 STUDY		
L Nov-30-87		# TELEPHONE CALL DR G BURKE, MRO	DJF	871449
		REQUESTED SUPPORTIVE CARE INFO ON PATIENTS WHO DIED DURING CONSOLIDATION THERAPY IN THE 3-74 & 3-603 LEUKEMIA STUDIES. ALSO WANTED HAZARD RATIOS FOR THE 3-603 SUBSET ANALYSES PROVIDED 11/24/87. ASKED THAT WE OFFICIALLY SUBMIT THE BREAST CA SUMMARY SENT TO THE ADVISORY PANEL TO THE NDA.		
L Dec-01-87		CORRESPONDENCE LIST OF LEDERLE PRESENTERS(NOVANTRONE)@ FDA ADV COMM MTG	DJF	871490
L Dec-01-87		# TELEPHONE CALL DR D HERSEY, SEC ONCOL DRUGS ADV COMM	DJF	871453
		DR DEAN BRENNER OF ROSWELL PARK WILL BE THE NEWEST MEMBER OF THE ADVISORY PANEL.		
L Dec-02-87		# TELEPHONE CALL DR G BURKE, MRO	DJF	871454
		DR S MARCUS CALLED ABOUT THE PRESENTATION OF SUPPORTIVE CARE DATA FOR PATIENTS IN THE 3-603 LEUKEMIA STUDY.		
L Dec-03-87		# TELEPHONE CALL DR G BURKE, MRO	DJF	871462
		PROVIDED DR BURKE WITH SURVIVAL HAZARD RATIOS ON SUBGROUPS OF PATIENTS FROM THE 3-603 LEUKEMIA STUDY REQUESTED ON 11/30/87.		

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L Dec-07-87 \* MEETING DJF 871524  
ONCOLOGIC DRUGS ADVISORY COMM MTG LEUKEMIA APPROVED

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEETING -  
NOVANTRONE APPROVED 7-2(2 ABSTAINING) FOR  
FIRST-LINE USE IN COMBO VS ANLL. 11-0 VOTE AGAINST  
ITS USE AS SINGLE USE IN RELAPSED ANLL. USE IN  
BREAST CANCER NOT APPROVED BY AN 8-3 VOTE.

F Dec-08-87 # MEETING DJF 871508  
DR G TURNER, OFFICE OF SCIENTIFIC INVESTIGATION

L Dec-09-87 \* RESPONSE TO FDA DJF 871520  
(a) CASE REPORT FORM /003-074-0  
RANDOM CRFs FROM #3-74 REQ BY DR G TURNER(FDA)FOR  
AUDITING

F Dec-09-87 # TELEPHONE CALL DJF 871527  
DR G BURKE, MRO

CALLED DR MARCUS RE WORDING OF THE PI RELATED TO  
THE CONSOLIDATION PHASE OF TREATMENT AND LISTING  
OF ADRS FOR THE INDUCTION PHASE IN STUDY 3-74.

L Dec-10-87 F Oct-15-87 RESPONSE TO FDA GRP 880030  
WE AGREE TO REQUESTED MODIFICATIONS TO ANALYTICAL  
TESTING

L Dec-10-87 \* RESPONSE TO FDA DJF 871521  
DRAFT LABELING FOR USE IN LEUKEMIA

(a) LABEL, DRAFT, PACKAGE INSERT  
PROP.DRAFTLABEL FOR ANLL + ADV REAC  
LIST(3=74/3-603)DR.BURKE

DRAFT LABELING FOR USE IN ANLL REFLECTING SEVERAL  
CONVERSATIONS WITH DR G BURKE WERE SUBMITTED TO  
FDA ALONG WITH A WANG DISKETTE.

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L Dec-10-87 F Oct-16-87 # CORRESPONDENCE GRP 880013  
WE AGREE TO SUGGESTED ANALYTICAL MODIFICATIONS

F Dec-11-87 # TELEPHONE CALL DJF 871528  
DR G BURKE, MRO

CALLED DRS MARCUS AND FOLEY SEVERAL TIMES RE THE FINAL LABELING FOR USE IN ANLL. FDA HAS MADE A NUMBER OF REVISIONS TO OUR PROPOSED TEXT SUBMITTED EARLIER IN THE DAY EG THE PK SECTION AND THAT DEALING WITH CARDIOTOXICITY.

F Dec-14-87 \* MEETING DJF 871539  
DR G BURKE, MRO & MS A SINDELAR, CSO

DRS CARTWRIGHT & SALETAN WERE ASKED TO STOP OFF AT THE ONCOLOGY DIV TO DISCUSS REVISIONS TO OUR PROPOSED PI SUBMITTED ON 12/11/97. AGREEMENT WAS REACHED ON REVISIONS.

F Dec-15-87 \* TELEPHONE CALL DJF 871540  
MS A SINDELAR, CSO

CALLED TO INDICATE TWO ADDITIONAL CHANGES TO PI RE SINGLE DOSE USE AND CHANGE OF LABEL FROM "FOR INJECTION" TO "INJECTION". WE EXPRESSED OUR OBJECTIONS TO THE LATTER REVISION FROM A SAFETY VIEWPOINT.

F Dec-23-87 \* APPROVAL DJF 880009  
APPROVAL FOR INITIAL RX OF ANLL IN COMBINATION

L Dec-30-87 # TELEPHONE CALL NAS 880007  
MR K FEATHER, DIR DIV DRUG ADVERTISING

APPROVED TRADEMARK NOVANTRONE MITOKANTRONE HCL FOR PRE-LAUNCH REMINDER AD.

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L Jan-04-88	# TELEPHONE CALL MS A SINDELAR, CSO	DJF	880008
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REVISED ADR TABLE AGREED TO FOR FINAL PRINTED  
LABELING.

F Jan-12-88	L Jan-05-88	* ACKNOWLEDGEMENT FDA ACKNOWLEDGES RECEIPT OF SUPP 1/12/88	S001	GRP	880132
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L Jan-20-88	L Dec-20-87	* SUPPLEMENT SUBMISSION OF PRESERVATIVE EFFICACY FOR MULTIPLE DOSE VIAL		GRP	880135
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